

In re Application of: SUN et al.

Serial No.: 10/054,935

Examiner: Susan Ungar, Ph.D

Filed: January 25, 2002

Group Art Unit: 1642

For: **BREAST CANCER TRANSCRIPTION FACTOR GENE AND USES**

**Declaration Under 37 C.F.R. §1.132**

1. I, Zairen Sun, Ph.D., am an inventor of the subject matter described and claimed in the above-identified U.S. Patent Application which is assigned to OriGene Technologies. I am also Director of Research and Development of OriGene Technologies, Inc

2. The following experiments were performed by me, or under my supervision.

3. Polyadenylated mRNA was isolated from normal breast and breast cancer tissue samples, and used as a template for first-strand cDNA synthesis. Samples were obtained from 12 different breast cancers, and 12 different normal breasts. The resulting cDNA samples were normalized using beta-actin as a standard. For the normalization procedure, PCR was performed on aliquots of the first-strand cDNA using beta-actin specific primers. The PCR products were visualized on an ethidium bromide stained agarose gel to estimate the quantity of beta-actin cDNA present in each sample. Based on these estimates, each sample was diluted with buffer until each contained the same quantity of beta-actin cDNA per unit volume.

4. To detect gene expression, PCR was carried out on aliquots of the normalized tissue samples using oligonucleotide primers specific for BCU1041:

ATTCTTGATGCCCCCTATCTCAAGAGGAA (forward primer), and

GAACATGGCAGGTGAGTAAAAGTTGACC (reverse primer). The reaction products were loaded on to an agarose (e.g., 1.5-2%) gel and separated electrophoretically. The lane at the far left of each panel contains molecular weight standards. See, attached Fig. 1.

5. As shown in attached Fig. 1, significant up-regulation of BCU1041 was observed in at least 8 of the 12 different tissue samples from breast cancers. The arrow indicates the expected position of the amplified segment of BCU1041 mRNA. In contrast, this product was absent in the normal breast cancer tissues.

6. I declare further that all statements made in this Declaration are of my own knowledge and are true and that all statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Date

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Zairen Sun